§ 121.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.[9] The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider the following:

(1) The CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories.'' This document is available on the National Select Agent Registry at *http://www.selectagents.gov/*.

(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR 1910.1200 and 1910.1450. This document is available on the National Select Agent Registry at *http://www.selectagents.gov/*.

(3) The ''NIH Guidelines for Research Involving Recombinant DNA Molecules.'' This document is available on the Internet at *http://www.selectagents.gov/*.

(d) The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.

(e) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61080, Oct. 5, 2012]

§ 121.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:

(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] <100 ng/kg body weight.

(b) The Administrator may revoke approval to conduct any of the experiments in paragraph (a) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(c) To apply for approval to conduct any of the experiments in paragraph (a) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61080, Oct. 5, 2012; 79 FR 26831, May 12, 2014]

§ 121.14 Incident response.[10]

(a) An individual or entity required to register under this part must develop and implement a written incident response plan[11] based upon a site specific risk assessment. The incident response plan must be coordinated with

[9] Technical assistance and guidance may be obtained by contacting APHIS.

[10] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

[11] Technical assistance and guidance may be obtained by contacting APHIS.

any entity-wide plans, kept in the workplace, and available to employees for review.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, and other natural and manmade events.

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

(d) The incident response plan must also contain the following information:

(1) The name and contact information (e.g., home and work) for the individual or entity (e.g., responsible official, alternate responsible official(s), biosafety officer, etc.);

(2) The name and contact information for the building owner and/or manager, where applicable;

(3) The name and contact information for tenant offices, where applicable;

(4) The name and contact information for the physical security official for the building, where applicable;

(5) Personnel roles and lines of authority and communication;

(6) Planning and coordination with local emergency responders;

(7) Procedures to be followed by employees performing rescue or medical duties;

(8) Emergency medical treatment and first aid;

(9) A list of personal protective and emergency equipment, and their locations;

(10) Site security and control;

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge; and

(12) Decontamination procedures.

(e) Entities with Tier 1 select agents and toxins must have the following additional incident response policies or procedures:

(1) The incident response plan must fully describe the entity's response procedures for failure of intrusion detection or alarm system; and

(2) The incident response plan must describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins.

(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61080, Oct. 5, 2012]

§ 121.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins; and

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored.

(b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.